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10/519,941	12/29/2004	Masaya Tanaka	0020-5615PUS1	5052	
2292 7590 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAM	EXAMINER	
			OSTRUP, CLINTON T		
			ART UNIT	PAPER NUMBER	
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## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail  $\,$  address(es):

mailroom@bskb.com

## Application No. Applicant(s) 10/519,941 TANAKA, MASAYA Office Action Summary Art Unit Examiner CLINTON OSTRUP 3771 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 29 February 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-8 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-8 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

1. Claims 1-8 are pending in this application.

### Response to Amendment

This Office Action is in response to the amendment filed February 29, 2008. As directed by the amendment, claims 1, 3, 6 & 7 have been amended.

#### Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 6, the phrases "sheet-like" and "film-like" renders the claim indefinite because the claims include elements not actually disclosed (i.e. those encompassed by "like"), thereby rendering the scope of the claims unascertainable.

Claim 7 is confusing because it is unclear what reference point is being used to determine the "portion of carbon dioxide in the supplied carbon dioxide gas is not less than 10%." Is it based on the total weight of the gas, the mole fraction of gas, or some other means for determining proportions?

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### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishino et al., (JP 07-171189).

Regarding claim 1, Nishino discloses a carbon dioxide external administration device (figure 1) comprising: a sealing enclosure member (1) for sealing a body surface from the outside air; the sealing enclosure member holds carbon dioxide gas within a sealed inside space; a supply means (2) for supplying carbon dioxide into the inside space of the sealing enclosure member; and an absorption aid (water) that is provided in the inside space of the sealing enclosure member, contains a carbon dioxide-dissolving medium (water) for dissolving carbon dioxide gas, and dissolves carbon dioxide gas to assist transdermal or transmucosal absorption of the carbon dioxide. See: [0008-0015] and figure 1.

Regarding claim 2, Nishino discloses a carbon dioxide external administration device having a carbon dioxide amount indicator (shower cap or boot) that expands upon carbon dioxide being supplied into the sealing enclosure member, and contracts by the decrease of carbon dioxide. See: figures 1 and 5.

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Regarding claim 3, Nishino discloses a carbon dioxide external administration device having a carbon dioxide absorption aid (water) that contains water as a carbon dioxide-dissolving medium.

Regarding claim 5, Nishino discloses a carbon dioxide external administration device with a carbon dioxide absorption aid (water) that contains a carbon dioxide dissolving medium comprising a viscous material containing at least water (The viscosity of water is 8.90 × 10<sup>-4</sup> Pa·s or 8.90 × 10<sup>-3</sup> dyn·s/cm<sup>2</sup> or 0.890 cP at about 25 °C).

Regarding claim 6, Nishino discloses a carbon dioxide external administration device with a sealing enclosure member (1 or 11) that is made from a flexible material having a shape holding ability, an elastic and flexible material, and a sheet-like or film-like material formed into a shower cap or a boot.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A), as applied to claims 1-3 & 5-6 above and further in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6.689.339).

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Regarding claim 4, Nishino teaches all the limitations of claim 4 except the carbon dioxide absorption aid as a sheet-like product impregnated with a liquid containing at least water.

Tanaka discloses carbon dioxide containing viscous compositions and that said compositions can be incorporated into a sheet for topically applying carbon dioxide gas to skin. See: col. 2, lines 36-col. 9, line 67.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus and method of applying carbon dioxide to skin, as discloses by Nishino by applying a sheet with a viscous carbon dioxide containing formulation, as taught by Tanaka, in order to provide enhanced delivery of carbon dioxide to the skin of a user.

Regarding claim 7, the combined references are silent regarding the percentage of carbon dioxide in the gas; however, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have optimized the percentage of carbon dioxide in the gas, since the general conditions are disclosed and discovering the optimum or workable ranges involves only routine skill in the art.

Regarding claim 8, the combined references teach a carbon dioxide external administration device with a carbon dioxide absorption aid that contains a carbon dioxide dissolving medium in the form of an emulsion or a cream and said emulsion or cream comprising at least an oil or fat, a surfactant and water. See: Tanaka et al., See: col. 2, lines 36-col. 9, line 67.

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#### Response to Arguments

 Applicant's arguments with respect to claim 1-8 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Moreover, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

#### Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zeppernick, (DE 20117745 U1); Konig (DE 3717582 A1); Rasor et al., (2002/0040205); Rasor et al., (6,652,479); Okura (JP 11-206437); Konig (DE 20307743 U1); Stenzler et al., (7,122,018); Piuk (WO 00/62733); and Kawagchi et al. (JP 08-182535 A) all of which are drawn to gas delivery devices.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/ Examiner, Art Unit 3771

/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771